REMARKS/ARGUMENTS

1. Amendments

Applicant has amended claims 4 and 15 to correct grammatical errors. Applicant has amended claims 28 - 34 to recite "the fusion molecule" rather than "the method". Claims 28 - 34 depend from claims 1, and 27 both of which claim a fusion molecule. No new matter is being added by these amendments. Claims 1-59 are now pending in the application.

2. Restriction Requirement

The Office Action indicates that restriction to one of the following inventions is required:

1. Claims 2 - 34 and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **myelin basic protein**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1, Class 435, subclass 810.

2. Claims 2 - 34 and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **proteolipid**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1, Class 435, subclass 810.

3. Claims 2 - 34 and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **myelin oligodendrocyte glycoprotein**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1, Class 435, subclass 810.

4. Claims 2 - 34 and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **αβ-crystallin**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1, Class 435, subclass 810.

5. Claims 2 - 34 and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **myelin associated glycoprotein**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1, Class 435, subclass 810.

6. Claims 2 - 34 and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **Po glycoprotein**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1, Class 435, subclass 810.

7. Claims 2 - 34 and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **PMP22, 2',3'-cyclic nucleotide 3'-phosphohydrolase**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1, Class 435, subclass 810.

8. Claims 2 - 34 and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **glutamic acid decarboxylase (GAD)**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1, Class 435, subclass 810.

9. Claims 2 - 34 and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **insulin**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1, Class 435, subclass 810.

10. Claims 2 - 34 and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **64 kD islet cell antigen (IA-2 or ICA512)**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1, Class 435, subclass 810.

11. Claims 2 - 34 and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **phogrin (IA-2β)**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1, Class 435, subclass 810.

12. Claims 2 - 34 and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **type II collagen**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1, Class 435, subclass 810.

13. Claims 2 - 34 and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **human cartilage gp39 (HCgp39)**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1, Class 435, subclass 810.

14. Claims 2 - 34 and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **gp130-RAPS**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1, Class 435, subclass 810.

15. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **myelin basic protein**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

16. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **proteolipid**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

17. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **myelin oligodendrocyte glycoprotein**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

18. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **αβ-crystallin**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

19. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **myelin associated glycoprotein**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

20. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **Po glycoprotein**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

21. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **PMP22, 2',3'-cyclic nucleotide 3'-phosphohydrolase**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

22. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **glutamic acid decarboxylase (GAD)**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

23. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **insulin**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

24. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **64 kD islet cell antigen (IA-2 or ICA512)**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

25. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **phogrin (IA-2β)**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

26. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **type II collagen**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

27. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **human cartilage gp39 (HCgp39)**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

28. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **gp130-RAPS**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

29. Claims 46-50, drawn to a method for treating autoimmune **rheumatoid arthritis** comprising administering an effective amount of at least one specific fusion protein, classified in Class 424, subclass 192.1.

30. Claims 46-50, drawn to a method for treating autoimmune **Type-I diabetes** comprising administering an effective amount of at least one specific fusion protein, classified in Class 424, subclass 192.1.

31. Claims 46-50, drawn to a method for treating autoimmune **Multiple Sclerosis** comprising administering an effective amount of at least one specific fusion protein, classified in Class 424, subclass 192.1.

32. Claims 46-50, drawn to a method for the prevention of symptoms resulting from a type I hypersensitive reaction and a method of prevention of a specific type I hypersensitivity disease in a subject comprising administering a specific fusion

molecule, wherein the second polypeptide is an allergen, classified in Class 424, subclass 192.1.

The Office Action indicates that linking claim 1 will be examined along with claims 2-34 and 40-44 should one of groups 1-14 be elected. Linking claim 35 will be examined along with claims 36-39 should one of groups 36-39 be elected. Linking claim 45 will be examined along with claims 46-50 should one of groups 46-50 be elected.

The Office Action indicates that Groups 1-28 are unrelated because they are not capable of use together and they have different modes of operation, different functions or different effects. In the instant case, the products allegedly differ with respect to their structures and physiochemical properties.

The Office Action indicates that Groups 29-32 are unrelated because they are not capable of use together and they have different modes of operation, different functions or different effects. In the instant case, the methods of treating distinct diseases using distinct products as claimed allegedly differ with respect to the etiology, treatment steps and therapeutic endpoints.

The Office Action indicates that Groups 1-28 and Groups 29-32 are related as product and process of use. In the instant case, the products claimed can be used in treating different diseases as claimed or materially different processes such as binding assays and identifying compound. The Office Action has indicated that where applicant elects claims directed to a product and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all of the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821.4.

Response

Applicant traverses the restriction requirement, because the restriction requirement is improper for the following reasons. In particular, Applicant traverses the restriction between groups 1 - 14 each drawn to a fusion protein. Applicant also traverses the restriction between groups 15 - 28 each drawn to a nucleic acid encoding a fusion protein. Finally Applicant traverses the restriction between groups 29 - 31 each drawn to a method for treating an autoimmune disease.

There are two criteria for a proper requirement for restriction between patentably distinct inventions (see MPEP 803):

1. The inventions must be independent (see MPEP § 802.1) or distinct as claimed (see MPEP § 806.05)

2. There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02)

Regarding the first criteria, the inventions are not independent. The term "independent" means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation or effect (MPEP 802.01).

It is submitted that independent claim 1 and dependent claims 2-34 and 40-44 are drawn to the same invention. As explained throughout the specification, a specific embodiment of the invention concerns fusion molecules in which a first polypeptide sequence is capable of specific binding to a native IgG inhibitory receptor comprising an ITIM motif, functionally connected to a second polypeptide sequence which sequence is an antigen. This fusion molecule is capable of indirectly binding to a native IgE receptor through a third polypeptide sequence. The third polypeptide sequence includes an immunoglobulin specific for the antigen sequence which binds to a native IgE receptor (FcεR). Accordingly, all of the fusion molecules claimed contain a common structure, i.e. the first polypeptide sequence. Secondly, the second polypeptide sequence in all of the fusion molecules is similar in that it is an antigen.

The Examiner has restricted the claims between the different proteins listed in claim 8 which is a Markush type claim. However, unity of invention exists where

compounds included within a Markush group share a common utility and share a substantial structural feature disclosed as being essential to that utility. In the instant case, the fusion molecules share a common utility since they are designed to treat autoimmune diseases and they share a common feature, the first polypeptide sequence linked to an antigen. The nucleic acids of claims 36 - 39 encode the fusion molecules and the methods of claims 46-50 use the fusion molecules. Accordingly, Applicant maintains that the restriction between groups 1 - 14, between groups 15 - 28 and between groups 29 - 31 is improper.

Regarding the second criteria, there is not a serious burden on the examiner if restriction is not required. For the purposes of the initial requirement, a serious burden may be shown by the Examiner if the Examiner shows with an appropriate explanation that the inventions have a separate classification or a separate status in the art or a different field of search. In the instant case, the Examiner has indicated that groups 1 - 14 are all classified in Class 530, subclass 350, Class 424, subclass 192.1 and Class 435, subclass 810. Groups 15 - 28 are all classified in Class 536, subclass 23.5, Class 435, subclass 320.1 and 252. Groups 29 - 31 are all classified in Class 424, subclass 192.1. Accordingly, the Examiner would be searching the same classes for each of the inventions. Applicant maintains that there is not a serious burden on the Examiner if restriction is not made.

Finally, the Examiner recognizes that the restriction between groups 1 - 14 is improper because the Examiner has indicated that claim 1 is a linking claim. MPEP § 809.03 defines a linking claim to be (a) a genus claim linking species, (b) a claim to the necessary process of making a product, (c) a claim to "means" for practicing a process and (d) a claim to the product linking a process of making and a use. In the instant case, claim 1 is linking species. The Examiner should have more properly requested Applicant to elect a species in claims 1 - 34 and 40-44 for examination, rather than restricting the claims between inventions.

Applicant maintains that the restriction between groups 15 - 28 directed to a nucleic acid encoding the fusion protein is improper for the same reasons set forth above. Applicant maintains that the restriction between groups 29 - 31 directed to a method of treatment is improper for the same reasons set forth above.

Applicant requests reconsideration and withdrawal or modification of the restriction requirement.

Applicant notes that the Examiner has indicated that where applicant elects claims directed to a product and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

Election

Applicant is required to make provisional election. Applicant provisionally elects, with traverse, the invention of Group 1 directed to claims 2 - 34 and 40 - 44 drawn to an isolated fusion molecule wherein the autoantigen is myelin basic protein.

Applicants believe that this application is in condition for allowance.

Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: August 24, 2004

Leslie A. Mooi
Reg. No. 37,047

HELLER EHRMAN WHITE & McAULIFFE LLP
Customer No. 25213
275 Middlefield Road
Menlo Park, California 94025
Telephone: (650) 324-7000
Facsimile: (650) 324-0638

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